

Planning, Implementing, and Evaluating Process Evaluations of Complex Interventions in Critical Care

An Interactive Workshop



CIHR IRSC

Canadian Institutes of Health Research Instituts de recherche
en santé du Canada

We acknowledge that we are on traditional territories in Alberta and British Columbia of the many First Nations, Métis, and Inuit whose footsteps have marked these lands for centuries.

Our experiences are located on the present day and ancestral territory of many peoples, including the Treaty 6, 7, and 8 territories. Namely: the Blackfoot Confederacy – Kainai, Piikani, and Siksika – the Cree, Dene, Sauteaux, Nakota Sioux, Stoney Nakoda, and the Tsuut’ina Nation and the Métis Nation of Alberta, as well as the unceded territory of the Ktunaxa and Secwépemc.

We make this acknowledgement as an act of gratitude to those whose territory we reside on or are visiting and as a step in the journey of reconciliation.



Sikomh Kokomii, Kamâmak, Suwatâga-Mu, and bb iskwew

We acknowledge the traditional territories upon which we gather; McMaster University is located on the traditional territories of the Mississauga and Haudenosaunee nations, and within the lands protected by the “Dish with One Spoon” wampum agreement”.

For many thousands of years, the first people sought to walk gently on this land, offering their assistance to the first European travelers and sharing their knowledge for survival in what was at times a harsh climate. We seek a new relationship with the original peoples of this land, one based in honour and deep respect.

May we be guided by love and right action as we transform of our personal and institutional relationships with our Indigenous friends and neighbours.

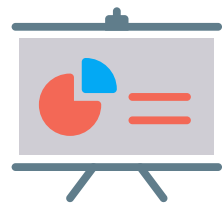


Morning Agenda



8:00-9:00 am

Introductions, overview of studies, discussion



9:00-10:00 am

Development of research questions

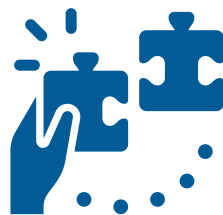


10:00-10:30 am



10:30-11:30 am

Development of data collection plans



11:30 -11:45 am

Check-in



11:45 am-2:45 pm

Logistics

- Washrooms are located to the left

For the 3 hour break (11:45 am - 2:45 pm)

- If you have a car, please let us know if you can drive people up to Lake Louise for activities:
 - Sightseeing gondola
 - Lake Louise lakefront
 - Hiking

Submitting your Expenses

- **Please retain all itemized receipts.**
- **If you are a McMaster employee, fill out the McMaster employee expense form**
- **If you are not a McMaster employee, fill out the non-employee expense report**
- **We will send you the appropriate forms after the meeting**

Introductions

Please tell us your
name and where you
are from!



Introductions

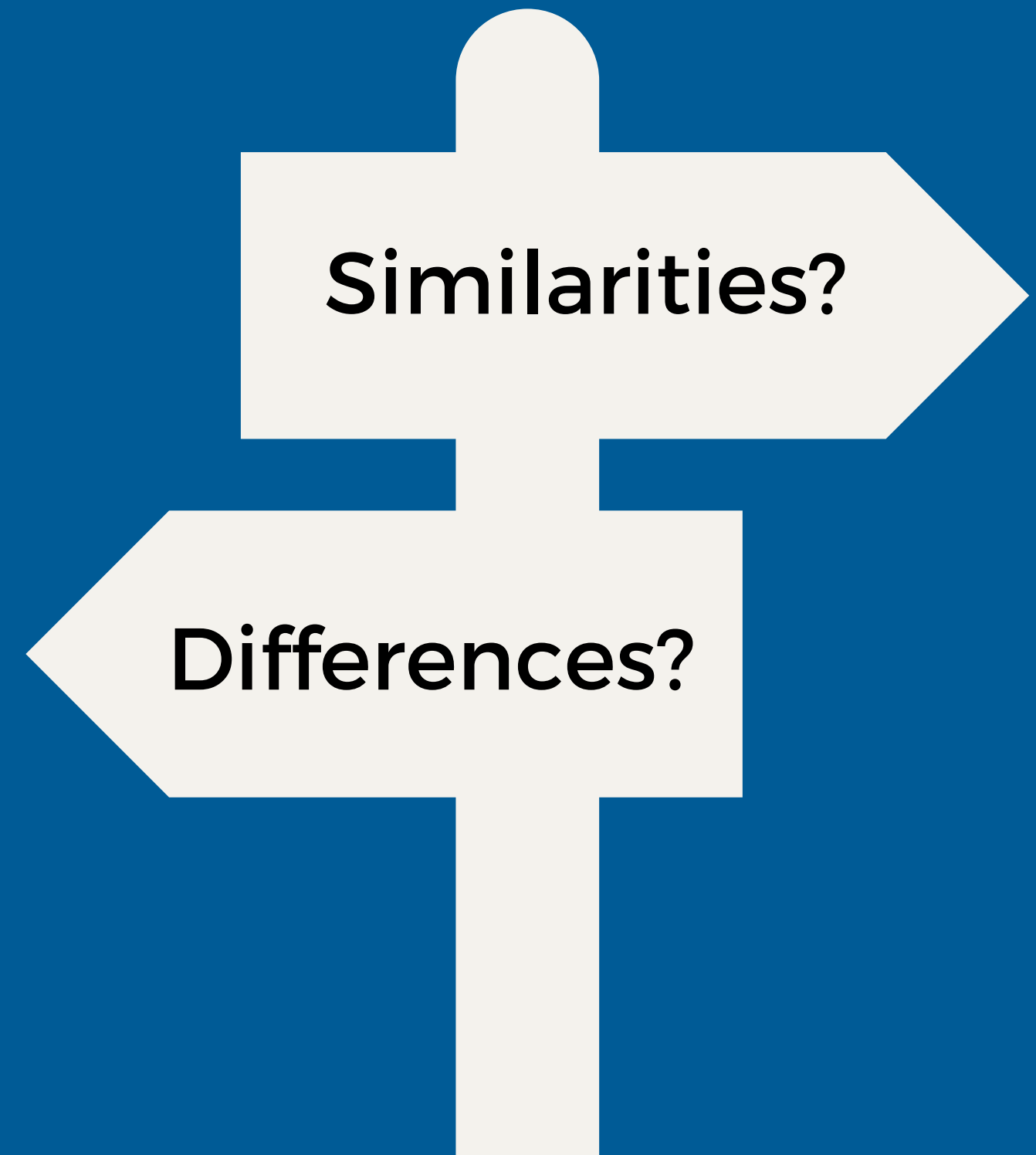


**Go to menti.com and join
with the code 9887 6694**

Overview of Studies



ICU Follow-Up Clinic



PICU Liber8: An Early Rehabilitation Implementation Study

K Choong, D. Fraser, A Al-Farsi, S Awlad Thani, S Cameron, C Cuello, S Debigaré, J Ewusie, K Kennedy, M Kho, K Krasevich, C M Martin, L Thabane, J Nanji, C Watts, A Simpson, A Todt, J Wong, F Xie, M Vu, C Cupido



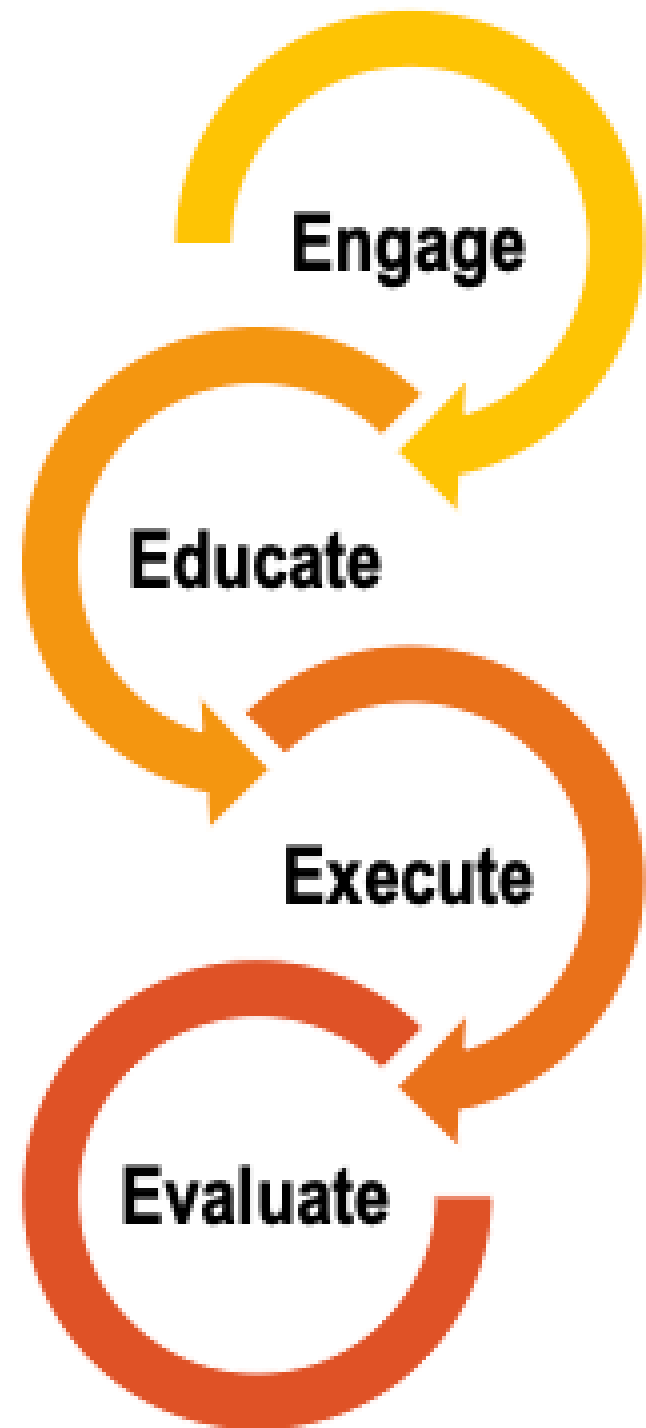
Primary Implementation Outcomes:

- ✓ Bundle adoption
- ✓ Factors influencing adoption
- ✓ Process of care: daily pt goal setting, sedative use, time to mobilization, RN workload, adverse events
- ✓ Resource Utilization

Secondary Clinical Patient Outcomes:

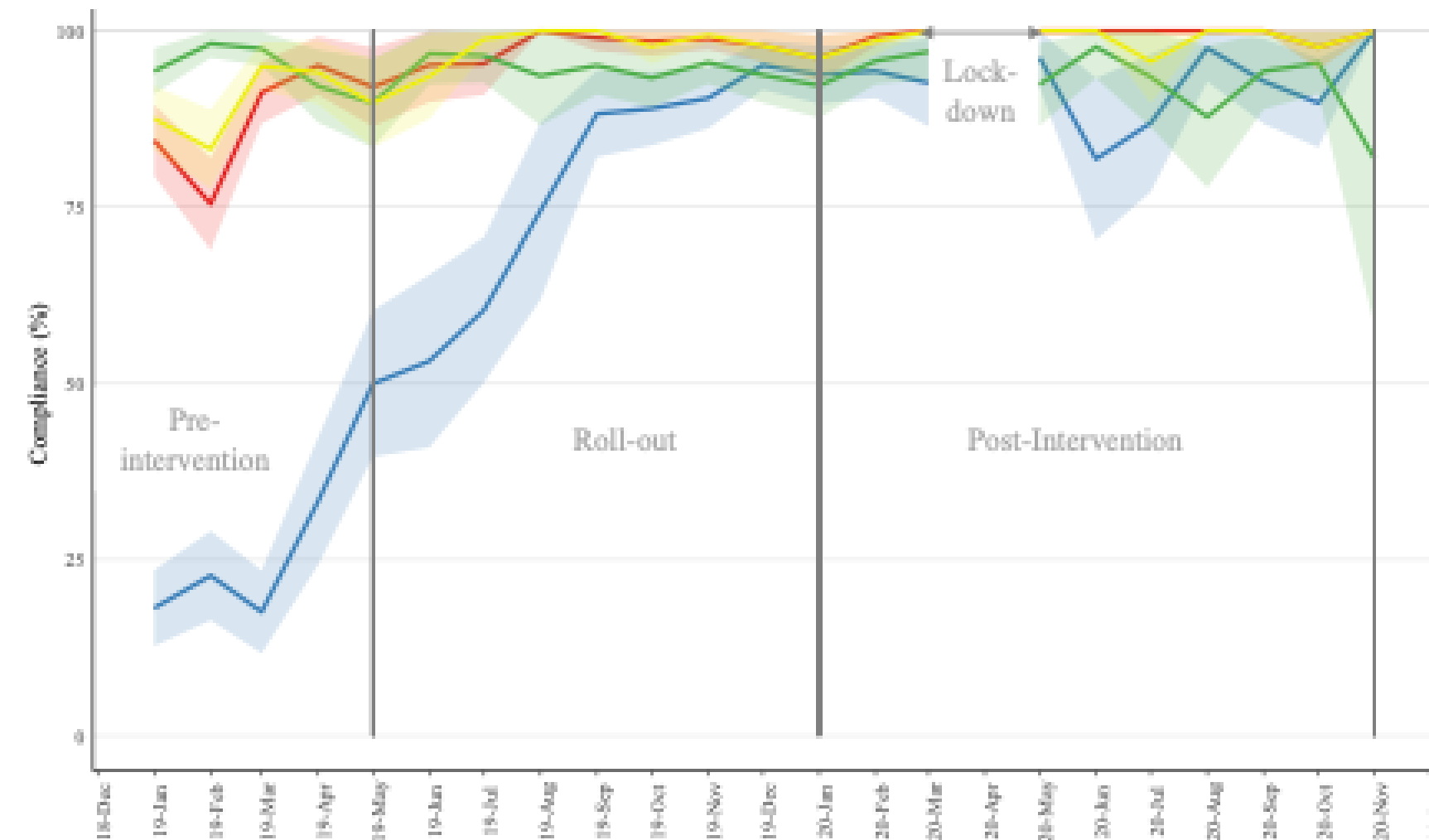
- ✓ PICU-based: delirium, withdrawal, LOS
- ✓ Post-PICU patient centered outcomes: Functioning, HRQL

Results: Uptake



- Implementation duration: 26 months (Aug '18 – Oct '20)
- Compliance was optimized (> 90%) within 3 months of Execution
- Compliance sustained 12 months post execution

Statistical process control charts for bundle compliance

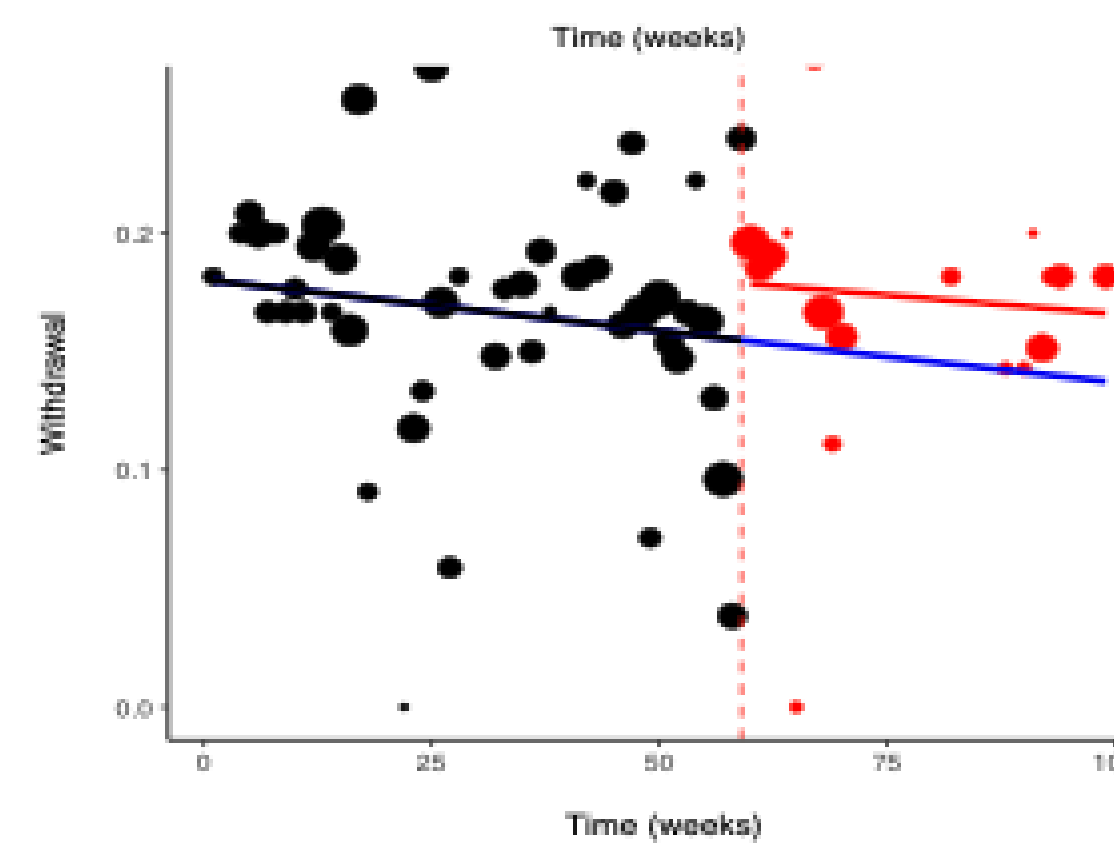
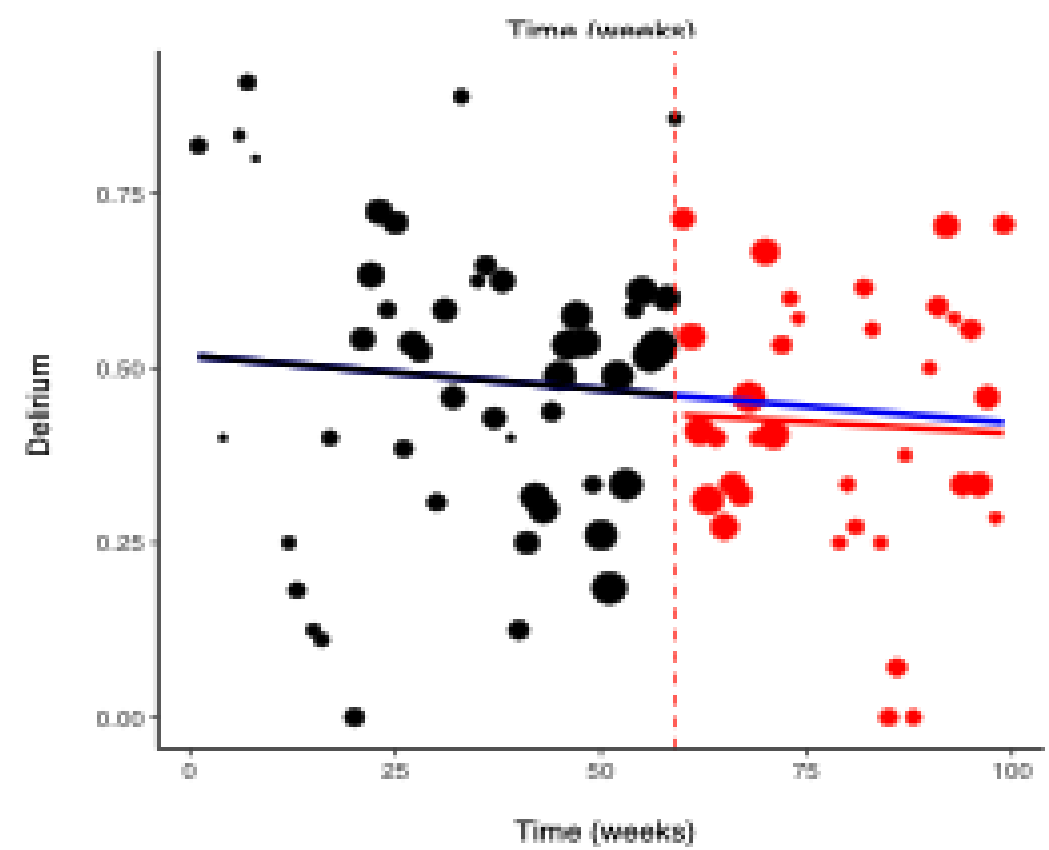
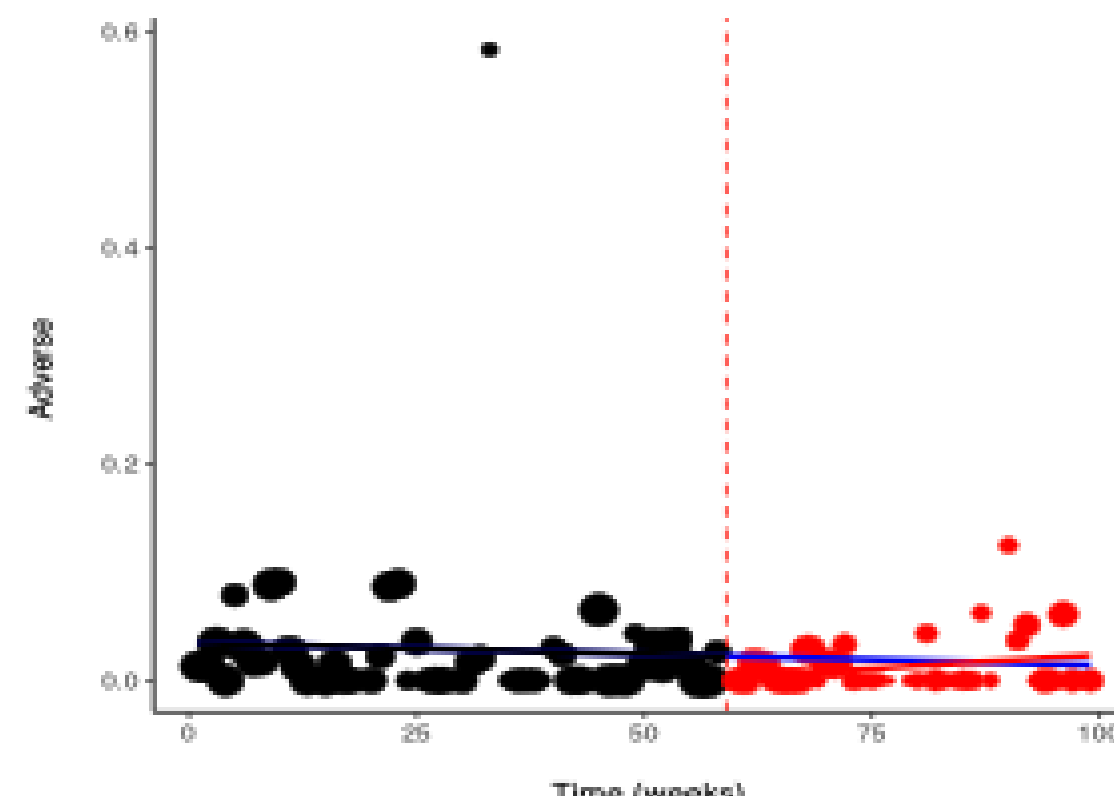
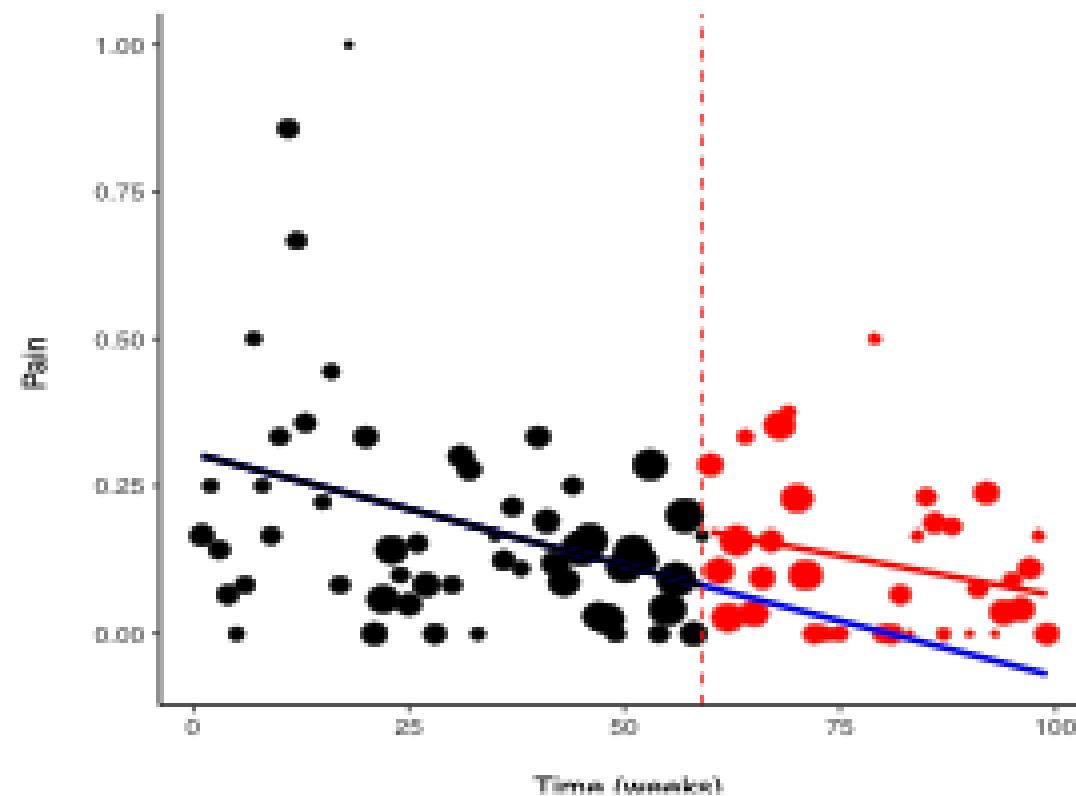


Results: Process of Care

Process of Care	Difference, 95% CI; p-value
Patient goal setting for allowing awakening; n (%)	↑ 46% ; p < 0.01
Early mobilization; n (%)	↑ 61% , 95% CI 44-77.3
Benzodiazepine exposure (<i>per 100 pt days</i>)	-23.2% , 95% CI (-30.8, -15.5), p = < 0.01
Opioid exposure (<i>per 100 pt days</i>)	-26.1% , 95% CI -34.8, -17.4); p = < 0.01
Dexmedetomidine exposure (<i>per 100 pt days</i>)	-9.2% , 95% CI (-18.1, -0.2); p = 0.05
Nursing workload (NIMS)	no increase ; p = NS

Results: Clinical outcomes

Interrupted time series analyses: no increase in significant pain or adverse events

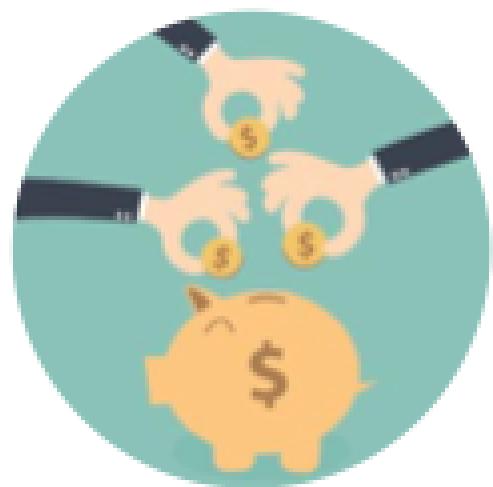


Results: Acceptability & Cost

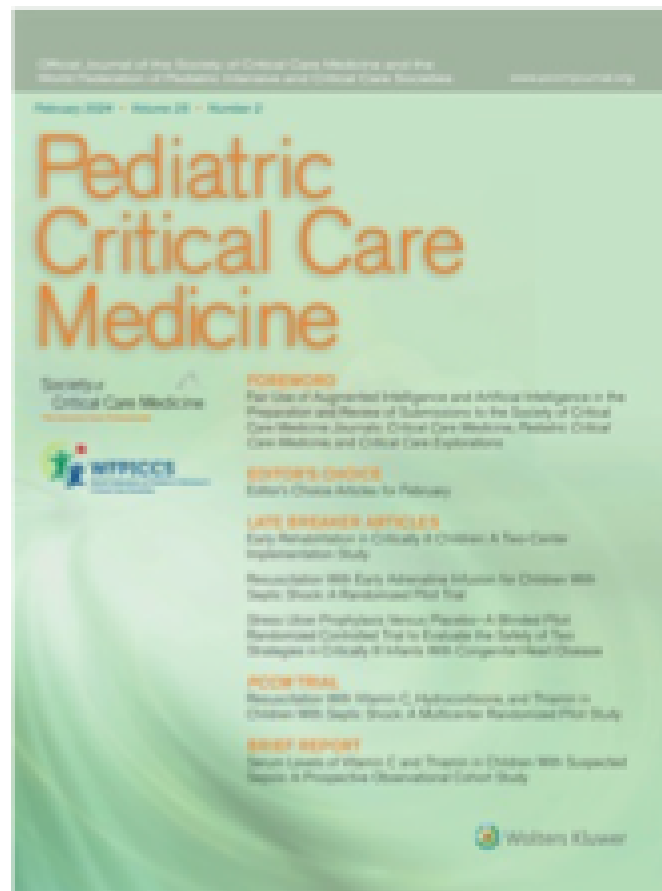


Staff and Family Acceptability increased from 48% to 99%

Qualitative focus group analyses identified barriers and facilitators to implementation.



McMaster Site	Pre Liber8	Post Liber8
	n=195; 842 patient days	n= 214; 830 patient days
Total Unit Costs	\$4,177, 175	\$3,758,457
Daily per patient cost	\$5640 (SD 4123)	\$4980 (SD 2300)



Karen Choong, MB, BCh^{1,2}
Douglas D. Fraser, MD, PhD³
Ahmed Al-Farsi, MD⁴
Safi Awlad Thani, MD⁵
Suzanne Cameron, MA⁶
Heather Clark, MSc PT⁷
Carlos Coufio, MD, PhD⁸
Sylvie Debigan, MA Psy⁹
Joycelyne Dewsis, PhD¹⁰
Kevin Kennedy, PhD¹¹
Michelle E. Kho, PT, PhD¹²
Kimberly Krasovich, BSc, BEd¹³
Claudio M. Martin, MSc, MD¹⁴
Lehana Thabane, PhD^{1,15}
Jasmine Nanji, MSc¹⁶
Catherine Wells, RN¹⁷
Andrea Simpson, RN¹⁸
Ashley Todd, RN¹⁹
Jonathan Wong, PharmD²⁰
Feng Xie, PhD²¹
Michael Vu, MD²²
Cynthia Cupido, MD²³
on behalf of the Canadian Critical
Care Trials Group

February 2024

LATE BREAKER ARTICLES

Early Rehabilitation in Critically Ill Children: A Two Center Implementation Study*

PCCM TRIALS

Post-Intensive Care Sequelae in Pediatrics—Results of an Early Rehabilitation Implementation Study

In Press; *Ped Crit Care Med* 2024

MANUSCRIPT IN PREP: Presented at CCF 2023

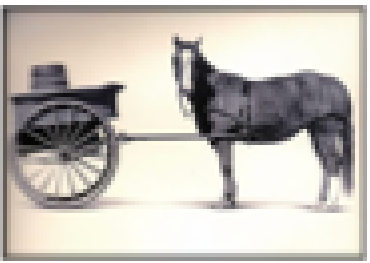
Early Rehabilitation Bundle Implementation in a Pediatric Intensive Care Unit – a Cost Analysis

Gertsman, Shira¹; Pavalagantharajah, Sureka¹; Falk, Lindsey¹; Borhan, Sayem²; Kennedy, Kevin³; Thabane, Lehana^{2,4,5}; Xie, Feng²; Cupido, Cynthia; Choong, Karen^{2,4}

- **Design:** 360 patient, multicenter, international open-label randomized trial
- **Population:** Medical-surgical adults within the first 4 days of mechanical ventilation
- **Intervention:** 30 minutes/ day of in-bed cycling + routine physiotherapy
- **Comparison:** Routine physiotherapy
- **Primary Outcome:** Physical Function ICU Test @ 3 days post-ICU discharge by blinded outcomes assessors



Improving Frailty, Outcomes and Recovery through Multifaceted Comprehensive Geriatric Assessment, Rehabilitation and Extended follow-up in older critically ill patients (INFORM CARE) Trial



P: Critically ill frail patients > 50 y.o.

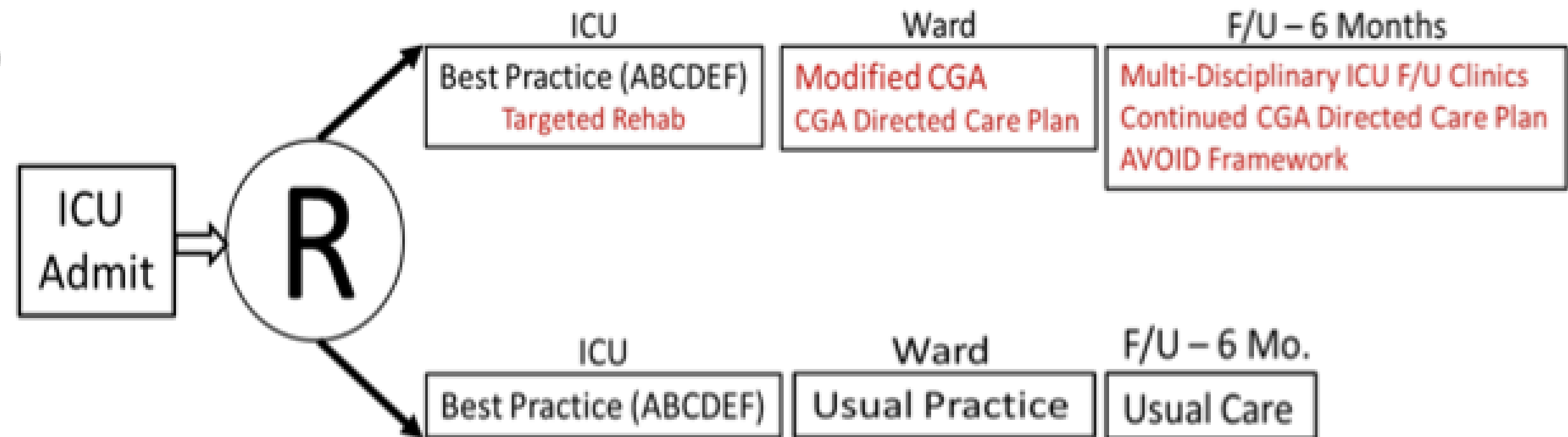
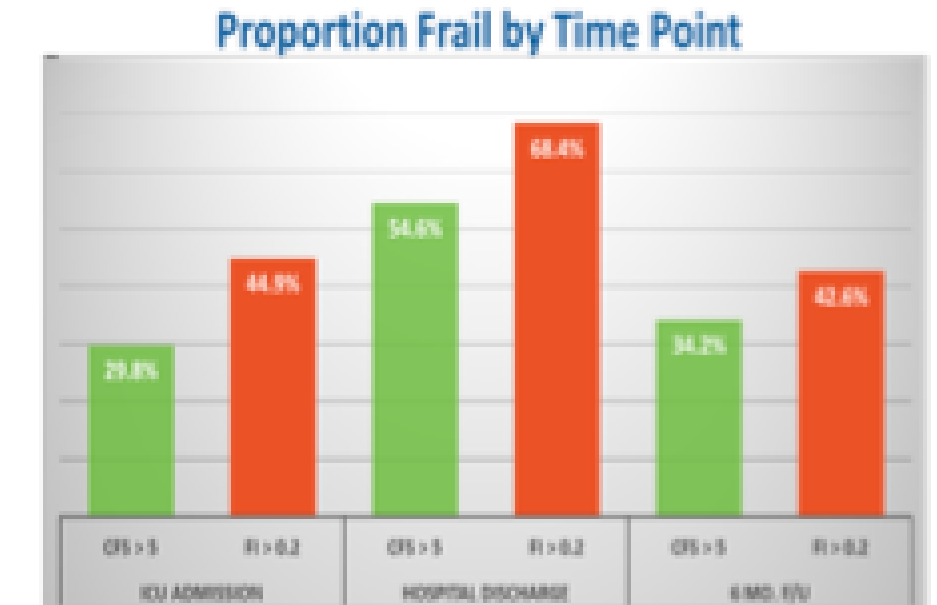
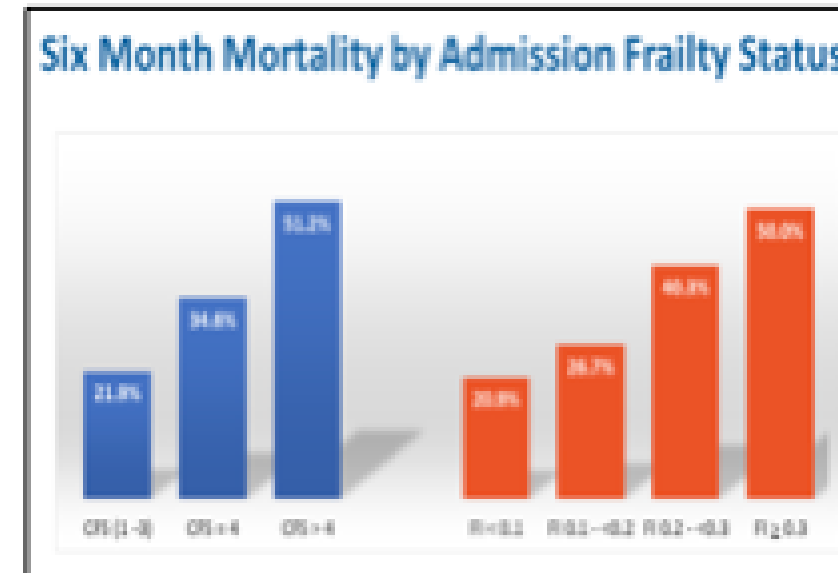
I: Complex, multifaceted, intervention

(mComprehensive Geriatric Assessment (FI), F/U Clinics, AVOID Framework)

C: Best Practice (ABCDEF)

O: Frailty level, HRQoL

T: Six Months



IMPACT-ICU

High risk ICU patient + caregiver

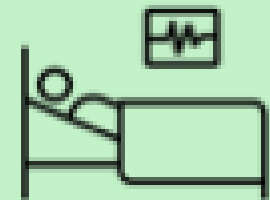
- >4d mechanical ventilation
- Tracheostomy
- >4d delirium
- No GP

Randomization
1:1

Usual Care

Intervention

6 months



In ICU:

- Information brochures on Post-ICU syndrome
- ICU diaries



3 months:

- multidisciplinary assessment (PT-OT-Pharmacist-SW-MD)
- Consultation prn

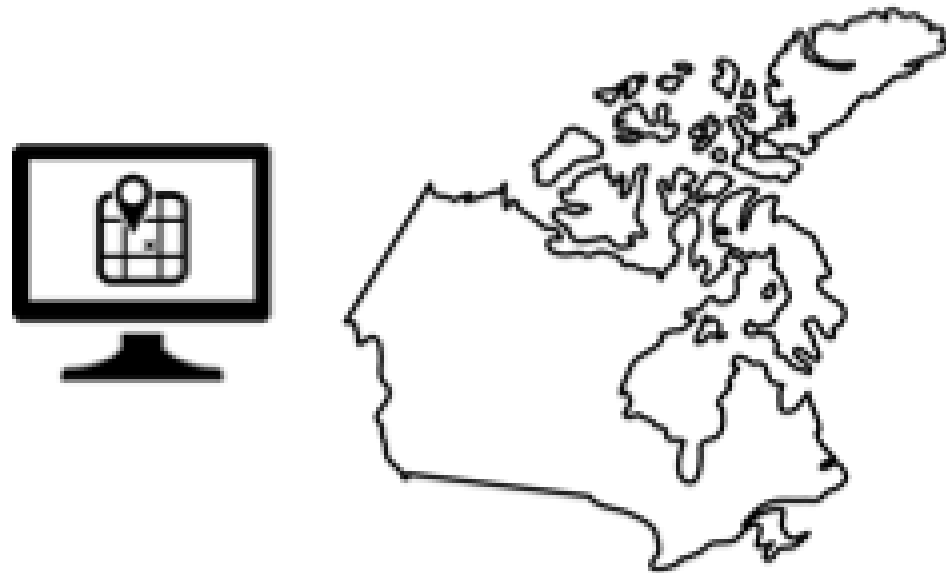


6 months:

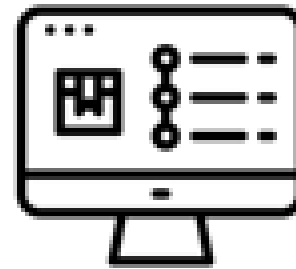
- multidisciplinary assessment (PT-OT-Pharmacist-SW-MD)
- Consultation prn

Outcomes: Primary: Feasibility, Secondary: Multimodal Assessment, Tertiary: Qualitative, Quaternary: Economic Analysis

Canadian Clinical Research Network



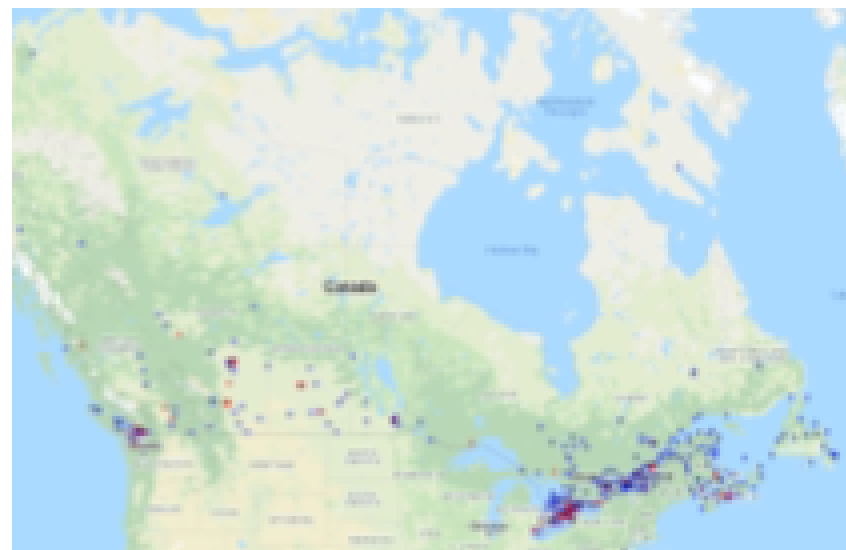
Acute care sites



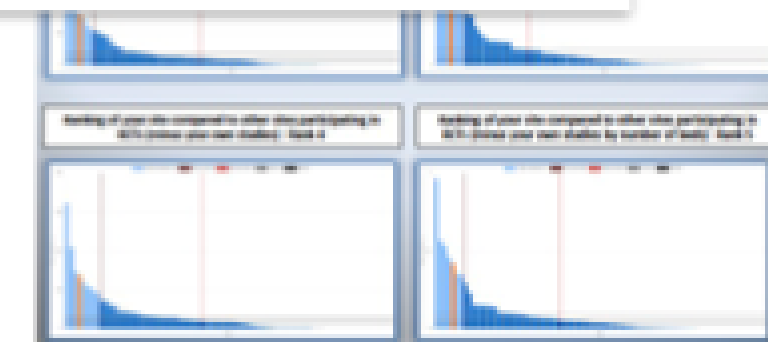
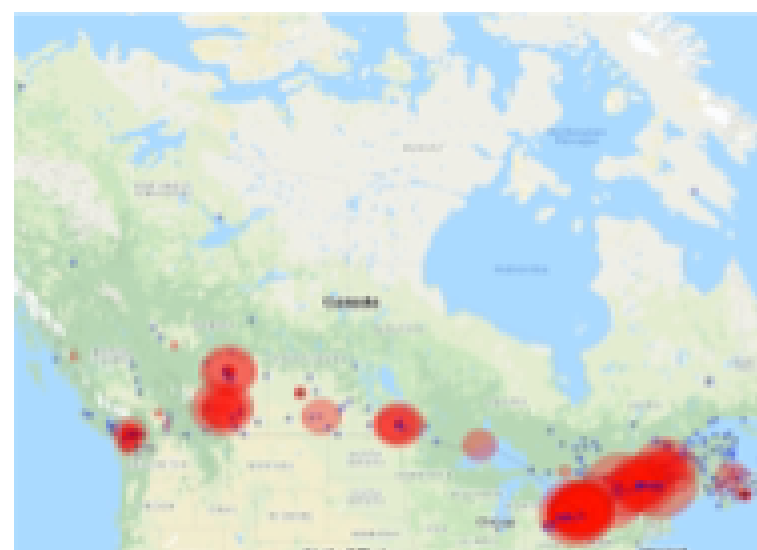
Clinical studies



Where *could* research occur in Canada?



Where *does* research occur in Canada?



Project Descriptions - Similarities

All studies focus on:

- Critical care patients
- Patient outcomes
- Patient quality of life

dfdf

Project Complexity - Similarities

- Multi-component interventions
- Longitudinal approach
- Involvement of several members of ICU care team
- Heterogenous studies

Project Successes - Similarities

- Engagement (champions, people who see the value/buy in)

Project Challenges - Similarities

- Unit-level barriers (staff turnover, funding)
- System-level barriers (ethics, leadership, data access)

Key Messages-Dr. Sharon Straus



- We can use different approaches to developing complex interventions and there is no single best approach
- We should use evidence and theory to develop complex interventions and consider feasibility of implementation within the particular context
- Different audiences (e.g. patients, the public, clinicians, managers, policy makers) can be the focus for different complex interventions

Key Messages-Dr. Janet Curran

THE FUNDAMENTALS OF PROCESS EVALUATION APPLIED TO COMPLEX INTERVENTIONS

Janet Curran PhD RN


Quality and Patient Safety Research Chair, IWK Health, Nova Scotia Health

Professor, School of Nursing, Dalhousie University





- Process evaluations can take many forms
- Always start with mapping out your understanding of how the intervention works
- Consult with intervention designers, implementers and end users early
- Focus on key uncertainties related to context, implementation and mechanisms of impact
- Choice of methods should align with your questions

Key Messages-Dr. Wanrudee Isaranuwatjai



Introduction to health technology assessment (HTA):

Planning, Implementing, and Evaluating Process Evaluations of Complex Interventions in Critical Care
Wanrudee Isaranuwatjai, PhD



- Don't run away from a health economist 😊 as our goal is to collaborate with clinical experts (like all the workshop attendees) and explore how economic evidence (through HTA) can be used to support their work and research :)
- Health care resources are scarce so we have to make choices
- When we have to make choices, would be great to have evidence to support
- HTA is one method/approach/tool to help create evidence package to support when we have to make choices
- HTA is a multidisciplinary approach which requires input and supports from all relevant stakeholders
- The overall goal of HTA is not to make a decision for us but to create evidence to inform policy- and decision-making process

Key Messages-Dr. Kirsten Fiest

Patient Engagement & Mixed Methods Research

Kirsten Fiest, PhD | Associate Professor
University of Calgary

- Patients and families are key groups to engage when planning and conducting a process evaluation (and all research for that matter!)
- Mixed methods and qualitative designs can be as rigorous as a quantitative design
- Don't be afraid of qualitative research! It can add richness and understanding to complex topics

Groups

Project	CYCLE	PICU Liber8	Frailty	ICU Follow-up	CCRN
Facilitators/ notetakers	Thérèse Poulin	Michelle Fung	Fatima Sheikh	Laurie Lee	Karla Krewulak
Leads	Michelle Kho	Karen Choong	John Muscedere	Gord Boyd	François Lamontagne
Trainees/staff	Heather O'Grady	Sherrie Orr	Carrie Shorey	Tasha Jawa	Marie-Hélène Masse
Attendees	Christine Fahim	Diane Heels- Ansdell	Laura Camposilvan	Amy Pastva	Lehana Thabane
	Lauren Vanderlelie	Kristy Obrovac	Andrew Seely	Christine Caron	Jackie Bosch
	Jessica Haines	Rebecca Porteous	Jenna Smith- Turchyn	Daana Ajami	Irene Watpool
				Christopher Grant	Julie Ménard

Development of Research Question



**Aims: Develop
the primary and
secondary
research
questions**



60 minutes



**One slide outlining
the research
question(s).
JC Slide 9, 11-13, 17-
18**

How to Approach this Session

1. Orient table to the project [Project Lead]
2. Review the definition of a process evaluation [All]
3. Share why a process evaluation is needed and what kind [Project Lead]
4. Brainstorm process evaluation core elements (MRC Framework) [All]
5. Generate primary and secondary research questions [All]

☀️ TIME FOR A ☀️
• BREAK •

Be ready to
start by
10:30 am

Development of Data Collection Plans



**Aim: identify
data sources for
the process
evaluation**



60 minutes



**One slide with data
sources;
JC slide 14, 16-17
KF slides 21-34
SS slides 9, 20-24, 34**

How to Approach this Session

1. What data do we have? [Project Lead]
2. What data do we need? [All]
3. How do we collect the data? [All]

dfdf

Check-In





**Lunch and
Leisure Time!**

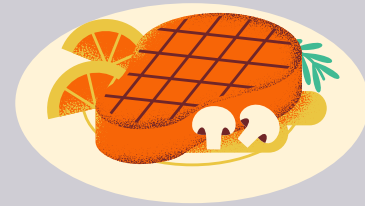
Please be
ready to start
by **2:45 pm**

Afternoon Agenda

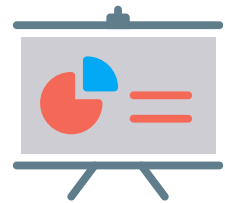


2:45-4:45 pm

Development of integrated analysis plans,
finalize presentations

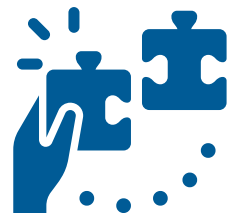


4:45 pm-5:15 pm



5:15-6:30 pm

Presentations



6:30-7:00 pm

Dessert, final reflections

THANK
YOU

Development of Integrated Analysis Plans and Group Presentations



**Aims: Develop
analysis plan & 5
min group
presentation**



2 hours



**7 presentation
slides max
KF slides 27-34
SS slides 39-40**

Slides to Include

1. Project background & purpose
2. Research question(s)
3. Data collection & sources
4. Integrated analysis plan



PLEASE be
ready to start
by **5:15 pm**



**You be the grant
panel!**

**Each group will
present their process
evaluation projects**

**5 min presentation
10 min group feedback**

Project Presentation Order

Time	Project
5:15 pm – 5:30 pm	CYCLE
5:30 pm – 5:45 pm	PICU Liber8
5:45 pm – 6:00 pm	Frailty
6:00 pm – 6:15 pm	ICU Follow-up
6:15 pm – 6:30 pm	CCRN

Presentation Judging Panel



Nicole Yada



Patricia Liaw



Ken Parhar

Workshop feedback



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DESSERT & REFLECTIONS



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